Public Health Service



Telephone: 206-486-8788 Fax: 206-483-4996

Food and Drug Administration Seattle District Pacific Region 22201 23rd Drive S.E. P.O. Box 3012 Bothell WA 98041-3012

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-28

Yeun Koo, President Finesse Fine Foods, Inc. 935 Industry Drive Tukwila, Washington 98188

WARNING LETTER

September 22, 1997

During an inspection of your firm, our investigator collected samples and labels of your "Sea Dog" brand products identified as: "Fish Frankfurter," "Salmon Frankfurter," "Jumbo Salmon Frankfurter," and "Chili Salmon Frankfurter," which are manufactured and distributed by your firm. The inspection, analytical results, and review of the labels, reveal that these products are misbranded within the meaning of section 403 of the Food, Drug, and Cosmetic Act (Act). These products are misbranded within the meaning of section 403(a)(1) of the Act, in that they fail to meet all requirements prescribed by Title 21, Code of Federal Regulations (CFR), Part 101-Food Labeling. "Sea Dog Fish Frankfurters" are misbranded within the meaning of section 403(a)(1) of the Act in that the number of grams of "protein" per serving declared on the label (7) is false and misleading because the product contains less than 80% of the declared amount.

"Salmon Frankfurters, Sea Dog Fish Frankfurters, Jumbo Salmon Frankfurters and Chili Salmon Frankfurters are misbranded in that the referral statement on the principal display panel adjacent to the "good source of protein," and "low in cholesterol" claims is not in a type size at least as large as the net quantity of contents declaration.

All of the labels bear nutrient content claims on the side panel that contains the name and place of business, but fail to bear a referral statement, "See _____ for nutrition information" with the blank filled in with the identity of the panel. The statement must be immediately adjacent to the term, "healthy," and the claims, "low in cholesterol" and "fat free" and for these labels, must be at least 1/8 of an inch [21 CFR 101.13 (g)(1) & (2)].

The above violations include nutrition labeling violations that concern certain new labeling requirements and are not meant to be an all inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Yeun Koo, President Finesse Fine Foods, Inc., Tukwila, WA 98188

Re: Warning Letter SEA 97-28

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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within thirty (30) working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Your response should include copies of the revised labels. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your reply should be addressed to: Food and Drug Administration, P.O. Box 3012, Bothell, WA 98041, Attention: Robert L. Wesley, Compliance Officer.

A copy of "A Food Labeling Guide," which contains the applicable sections of the food labeling regulations referred to in this letter, is enclosed for your review and information. The guide should help in correcting some of the format deviations noted in our review, to include: the heading "% Daily Value is not located over percent DV column and is not separated from information on calories by a bar. The nutrients are not declared in bold type, the information on calories is not separated from the heading: "Amount Per Serving" by a hairline as required by 21 CFR 101.9(d).

Sincerely,

Roger/L.'Lowell
District Director

Enclosure:

A Food Labeling Guide

cc: Washington State Dept. of Agriculture

Food Safety & Animal Health Division M/S AX-41

P.O. Box 42560

Olympia, Washington 98504-2560